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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,070	03/31/2004	Bharat Lagu	PRD 2050 NP	5510

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EXAMINER	
CHANG, CELIA C	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/814,070	LAGU ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *32-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of Group I where n=1, the piperidinyl compounds and the species of 3-[[(phenylamino)carbonyl]amino]-4'[4-(phenylmethyl)-l- piperidinyl]-benzamide, in the reply filed on Oct. 2, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

Claims 29-30 and claims 1-28, 31 wherein n=1 is prosecuted. Claims 32-37 and the remaining subject matter of claims 1-28, 31 are withdrawn from consideration per 37 CFR 1.142(b).

2. Claims 1-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement as well as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention; as well as the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

The specification was given a thorough analysis as to the description of the compounds for how to use such in a therapeutic process.

The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916), where the Supreme Court looked to whether the experimentation needed to practice an invention was undue or unreasonable. *Id.* An invention must be described so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*,

858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). As stated in the MPEP 2164.01(a) "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". The analysis must consider all the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole. *Id.* at 740, *Id.* at 1407. The factors to be considered herein are those set forth as the In re Wands, 8 USPQ 2nd 1400 (1988) decision.

The analysis is applied to the instant case.

Nature of invention

A very large number of compounds having modulating activity of phospholipase modulation activity. The large groups of Markush compounds do not share a substantial structural feature which is responsible for the disclosed utility. It is unclear what is the disclosed utility because the specification described that certain compounds have modulating activity which is both enhancing and inhibiting phospholipase.

The state of the art and predictability

In the specification on page 4, it was described that the compounds have PLC ß2 modulating activity and the PLC ß2 functions down stream of several chemokine receptors. Therefore, the end use depends on which chemokine receptor is involved. Chemokine (one kind of cytokine) receptor function has been well known in the art to be highly diverse and "....to date there is only limited understanding of the mechanisms that lead to one activity over another when a *specific* cytokine (chemokine) is involved....." Cytokine signaling has been further described in the Murashov's physiology over the Web that, for even a single inflammatory response, to involve highly complexed and complicated mechanisms. Nowhere in the specification was *any* particular physiological system or mechanism was described.

In the specification on page 5, first paragraph, description of structurally related compound which have diverse biological activity was provided. None of the described compounds has PCL ß2 modulating activity.

While prior art has well recognized that the binding of compounds to PLC enzyme are very complexed and require detailed description, for example, allosteric binding (CA 125:161854), region of binding (CA 140:36098), solubility/bioavailability of the compound, and interaction of PLC and other receptors (CA 144:286248), are all contributing factor to the compound PLC enzyme binding for which no description as to the anatomical location, nature and region of binding can be found.

The amount of guidance and working examples

The specification while prepared some compounds and provided IC50 values of selected compounds in the table of pages 78-79, there is no description as to what the binding constitutes in therapeutic functionality. The IC50 values were the inhibitory concentration for 50%

inhibition of the stimulating of guanine nucleotide binding in bovine eyes retinol rod outer cell membrane. Nowhere does this membrane measurement provided nexus to how to use the compounds for a particular end result.

The specification provided no guidance in subject selection, dosage formulation, site of administration and the results will be achieved after administration. While examples of compounds and their synthesis are provided, no guidance as to what and how the compounds can be used for an intended therapy.

A thorough search of the prior art revealed that structurally similar old compounds in addition to those mentioned on page 5, do not share any similar utility as the claims (see CA 138:122861 or CA 145:134355).

The deficiency of the specification as delineated supra coupled with the complexity and the high degree of unpredictability of the prior art evidenced the lack of description and enablement for the claimed compounds. Section 112 requires the application itself to inform, not to direct others to find out for themselves. In re Gardner 166 USPQ 138; Cross et al. v. Lizuka 224 USPQ 739; Ex parte Dash 27 USPQ2d 1481; Ex parte Aggarwal 23 USPQ 2d 1334.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Dec. 5, 2006

Celia Chang
Primary Examiner
Art Unit 1625